

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING )  
PHARMACY, INC. PRODUCTS LIABILITY )  
LITIGATION )  
\_\_\_\_\_ )

MDL No. 2419  
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO: )

Wray v. Ameridose, LLC, et al )  
1:13-cv-12737 )  
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STOPNC DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION  
FOR QUALIFIED PROTECTIVE ORDER

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Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD (collectively "STOPNC Defendants") file this Reply Memorandum in Support of their Motion for Qualified Protective Order [Doc. 50] and in response to the Plaintiffs' Brief in Opposition [Doc. 55].

**Law and Argument**

**A. Introduction and Summary of Argument**

This dispute involves the ability of Defendants' counsel to conduct *ex parte* interviews with the Plaintiffs' treating health care providers, just as Plaintiffs' counsel can. The dispute can be distilled to two issues: (1) whether Tenn. Code Ann. § 29-26-121(f) (hereinafter, at times, "-121(f)") is a substantive or procedural statute; and (2) whether -121(f) is preempted by the Health Insurance Portability and Accountability Act ("HIPAA").

**EXHIBIT 1**

As to the first issue, Tenn. Code Ann. § 29-26-121(f) is clearly substantive law. The Plaintiffs' opposition failed to analyze the statute under the *Hanna* test, incorrectly asserts that merely being related to pre-trial discovery classifies a statute as procedural, and ignores that fact that other sections of the Tennessee Health Care Liability Act that are related to pre-trial discovery have been found to be substantive law.

As to the second issue, the Plaintiffs ignore the fact that *both* HIPAA *and* Tenn. Code Ann. § 29-26-121(f) permit the disclosure of protected health information in this setting and that Tennessee courts facing this question have already concluded that HIPAA does not preempt -121(f). Further, the Plaintiffs' assertion that a full preemption analysis was not conducted is quickly exposed as incorrect when the opinions at issue are actually examined.

Therefore, this Court should grant the Defendants' Motion pursuant to Tenn. Code Ann. § 29-26-121(f) and permit *ex parte* interviews with the Plaintiffs' health care providers.

Alternatively, even if this Court finds that -121(f) is procedural and, thus, Fed. R. Civ. P. 26(c) controls, the Court *still* should issue a qualified protective order permitting the interviews because (1) the Court has the authority to do so and (2) HIPAA expressly allows it.

Lastly, if the Court applies a more traditional Rule 26(c) analysis, the Plaintiffs incorrectly state that the Defendants failed to show good cause for permitting *ex parte* interviews. They ignore the fact the parties are not on a level playing field as the Plaintiffs' counsel are free to communicate *ex parte* with their treating physicians, but the Defendants' counsel are not given the same opportunity without an order.

Despite the accusations that the Defendants intend to use the *ex parte* interviews for purposes “far beyond gathering information”<sup>1</sup> in order to “gain an unfair advantage in the discovery process,”<sup>2</sup> the Defendants seek only to remedy the inequity that currently exists in terms of access to the providers, a distinctly unfair advantage that favors the Plaintiffs. These treating providers have information relevant to the cases that the Defendants would like to discover in a cost-effective manner through informal interviews of the potential witnesses. And, the Defendants would like to do so *ex parte*, just like Plaintiffs’ counsel, to allow them to freely discuss the case with the witness, without the presence of opposing counsel, just as with any other non-party witness.

This inequity and the need to informally interview these potential witnesses is good cause for the Court to grant the Defendants’ Motion under Rule 26(c), with or without application of Tenn. Code Ann. § 29-26-121(f).

#### **B. Tenn. Code Ann. § 29-26-121(f) is Substantive Law**

In their original Motion, the Defendants applied the two-pronged *Hanna* analysis to establish that Tenn. Code Ann. § 29-26-121(f) is substantive law, an analysis the Plaintiffs fail to undertake. Rather, the Plaintiffs assert that because -121(f) relates to a discovery issue, it is automatically procedural law. This is incorrect.

Multiple courts have determined that issues related to pre-trial discovery and the presentation of the evidence in the case involve substantive issues of state law. For example, courts have applied substantive state privilege law when state law supplies the rule of decision<sup>3</sup> and substantive state law to identify the elements necessary to

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<sup>1</sup> Doc. 55 at 2.

<sup>2</sup> *Id.*

<sup>3</sup> See Fed. R. Evid. 501. (“state law governs privilege regarding a claim or defense for which state law supplies the rule of decision.”); *Lora v. Board of Ed. Of City of New York*, 74 F.R.D. 565, 576 (E.D. N.Y.

establish *res ipsa loquitur*.<sup>4</sup> Despite the Plaintiffs' contention otherwise, merely having some connection to pre-trial discovery is not enough for a statute to automatically be classified as procedural law.

Further supporting the Defendants' position, federal courts have found other sections of the Tennessee Health Care Liability Act ("THCLA")<sup>5</sup> to be substantive state law. Specifically, those sections related to pre-suit notice, certificates of good faith, and expert witness requirements have all been deemed substantive law in federal courts.<sup>6</sup>

Because other sections of the THCLA related to pre-trial activities and the way a health care liability action is litigated have been determined to be substantive law, it logically follows that -121(f) is substantive, too.

The Defendants have established that -121(f) is substantive law under the *Hanna* analysis in their original Motion. The Plaintiffs' general characterization of any issue related to the way a case is litigated pre-trial as procedural is likewise not consistent with the application of the procedural versus substantive tests. Put simply, Tenn. Code Ann. § 29-26-121(f) is substantive law and should be applied in these state law tort claims.

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1977) (if a state holds out the expectation of protection to its citizens via state recognized privileges, those protections should not be trumped by "a mechanical and unnecessary application of the federal rule").

<sup>4</sup> See *Kicklighter v. Nails by Jannee, Inc.*, 616 F.2d 734, 739 (U.S. Ct. App. 5<sup>th</sup> Cir. 1980) ("*res ipsa loquitur* is a rule of evidence which allows the jury to infer, from circumstantial evidence, negligence on the part of the defendant...the substantive law of Georgia determines which elements are required for the application of the doctrine...in this case.>").

<sup>5</sup> Tenn. Code Ann. § 29-26-101, *et seq.*

<sup>6</sup> See *Miller v. Monroe County, Tenn.*, 2010 WL 1427298 \* (E.D. Tenn. April 7, 2010) (the pre-suit notice requirements of Tenn. Code Ann. § 29-26-121(a), -121(b), and -122 are substantive law); *Williams v. U.S.*, 754 F. Supp. 2d 942, 953 (W.D. Tenn. 2010) (the certificate of good faith requirement of Tenn. Code Ann. § 29-26-122 is substantive, not procedural law); *Legg v. Chopra*, 286 F.3d 286, 292 (6<sup>th</sup> Cir. 2002) (the requirements in Tenn. Code Ann. § 29-26-115 for an individual to qualify as an expert witness are substantive law).

### **C. Tenn. Code Ann. § 29-26-121(f) is Not Preempted by HIPAA**

As a threshold matter, the Defendants adopt and incorporate the State of Tennessee's Memorandum of Law in Support of Tenn. Code Ann. §29-26-121(f).<sup>7</sup> The Defendants offer a few additional points below.

Federal statutes preempt all "contrary" state laws.<sup>8</sup> A state law is contrary if it fails one of two tests, the "impossibility test" or the "obstacle test."<sup>9</sup> The Plaintiffs acknowledge Tenn. Code Ann. § 29-26-121(f) passes the "impossibility test,"<sup>10</sup> but assert that -121(f) is preempted because it fails the "obstacle test," *i.e.* that -121(f) "stands as an obstacle to the accomplishment and execution of the full purposes and objective of Congress."<sup>11</sup>

As clearly outlined in the State of Tennessee's Memorandum, -121(f) is not preempted by HIPAA because (1) HIPAA permits (just as -121(f) does) the disclosure of protected health information in a judicial proceeding, and (2) -121(f) does not stand as an obstacle to the accomplishment of HIPAA's objections.

HIPAA expressly authorizes a covered entity to disclose protected health information in the course of a judicial or administrative proceeding.<sup>12</sup> Specifically, a covered entity (like a physician) can reveal protected health information in response to a court order or if reasonable efforts have been made to provide notice to the patient or reasonable efforts have been made to secure a qualified protective order.<sup>13</sup> A qualified

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<sup>7</sup> Doc. 59.

<sup>8</sup> See 45 C.F.R. § 160.203.

<sup>9</sup> See 45 § 160.202.

<sup>10</sup> Doc. 55 at 9.

<sup>11</sup> See 45 C.F.R. § 160.202

<sup>12</sup> See 45 C.F.R. § 164.512.

<sup>13</sup> See 45 C.F.R. § 164.512(e)(1)(ii)-(v).

protective order issued pursuant -121(f) permitting *ex parte* interviews does not stand as an obstacle to the purpose of HIPAA as the statute itself expressly permits the disclosure of protected health information under certain circumstances.

Finally, the Western District of Tennessee has already determined that HIPAA does not preempt -121(f). As is well explained in the State of Tennessee's Memorandum, the court in *Lovelace v. Pediatric Anesthesiologists, P.A.*, No. 2:13-cv-02289-JPM-dkv (W.D. Tenn. February 5, 2014), clearly performed a full preemption analysis, including analysis of the obstacle test, when it concluded that -121(f) was not preempted by HIPAA.

Therefore, the Defendants' Motion should be granted as HIPAA expressly allows the disclosure of protected health information in the context of a judicial proceeding and the Plaintiffs have provided nothing to adequately support their contention that HIPAA preempts -121(f).

**D. In the Alternative, the Court has the Authority to Permit *Ex Parte* Interviews Under Fed. R. Civ. P. 26(c)**

Alternatively, *ex parte* interviews are permissible, even if the Court determines that Tenn. Code Ann. §29-26-121(f) is procedural law. The Court should grant the Defendants' Motion pursuant to Fed. R. Civ. P. 26(c) and its inherent authority to govern discovery in this litigation.

First, assuming *arguendo* that -121(f) is procedural and not applicable in federal court, Fed. R. Civ. P. 26(c) governs the issuance of protective orders in this matter.<sup>14</sup>

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<sup>14</sup> Alternatively, if the Court finds that -121(f) contains both substantive and procedural elements, it may still apply the substantive portion of the statute (the right to conduct *ex parte* interviews), while deferring to the federal procedure for requesting a protective order (application to the Court and a showing of good faith). See *In re Johnson* 453 B.R. 433, 438-39 (M.D. Fla. 2011) (applying federal procedural statute permitting the pleading of punitive damages in an initial complaint and applying the state substantive

Second, as the Defendants have repeatedly pointed out, HIPAA expressly permits the disclosure of protective health information in a judicial proceeding, and there is no federal rule or statute prohibiting *ex parte* interviews. In the absence of such a prohibition, the Court is free to wield its inherent authority to control and direct the conduct of this litigation.<sup>15</sup> This inherent authority extends to a court's ability to control protective orders.<sup>16</sup>

The Court should grant the Defendants' Motion even if -121(f) is deemed procedural. The Defendants have satisfied the Rule 26(c) requirement of demonstrating good cause for why the Qualified Protective Order is necessary, granting the Defendants' Motion would fulfill -121(f)'s purpose – even if -121(f) is not specifically applied here – of leveling the playing field to provide equal access to the Plaintiffs' health care providers.

### **Conclusion**

Regardless of whether state or federal law applies to this dispute, this Court should grant the Defendants' Motion for Qualified Protective Order and permit *ex parte* interviews with the Plaintiffs' health care providers.

Tenn. Code Ann. § 29-26-121(f) is a substantive law that conveys a right. Merely being related to the pre-trial development of a case does not automatically classify a statute as procedural. Consistent with that approach, federal courts have deemed other sections of the THCLA to be substantive law.

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statute detailing the burden of proof required to make such a pleading); *Kicklighter v. Nails by Jannee, Inc.* 616 F.2d 734, 740 (U.S. Ct. App. 5<sup>th</sup> Cir. 1980) (applying the state substantive elements of *res ipsa loquitur* and the federal procedural statute for testing the sufficiency of the evidence to justify the claim).

<sup>15</sup> See *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 782 (1<sup>st</sup> Cir. 1988) (a court has the inherent power to modify discovery-related protective orders).

<sup>16</sup> See *U.S. v. Bulger*, 283 F.R.D. 46, 53 (D. Mass. 2012) (a court has the inherent authority to control the discovery process including the ability to modify a protective order).

Further, -121(f) is not preempted by HIPAA as the disclosure of protected health information in judicial proceedings is expressly authorized by the statute and no aspect of -121(f) stands as an obstacle to the accomplishment of HIPAA's goals.

Even if this Court determines that -121(f) is procedural, the Defendants' Motion should still be granted pursuant to Fed. R. Civ. P. 26(c). Whether under state or federal law, this Court should Grant to Defendant's Motion and enter a qualified protective order permitting *ex parte* interviews with the Plaintiffs' health care providers to establish an equitable playing field in this litigation.

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**

/s/ Chris J. Tardio

**C.J. Gideon, Jr.\***

**Chris J. Tardio\***

**Alan S. Bean\*\***

**Matthew H. Cline\***

315 Deaderick Street, Suite 1100

Nashville, TN 37238

Ph: (615) 254-0400

Fax: (515) 254-0459

[chris@gideoncooper.com](mailto:chris@gideoncooper.com)

***Attorneys for the Tennessee Clinic  
Defendants***

\* Admitted pursuant to MDL Order No. 1.

\*\* Admitted *pro hac vice*.



**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this \_\_\_\_\_ day of February, 2016.

/s/ Chris J. Tardio

**Chris J. Tardio**